REMARKS

Claim 23 has been amended to correct the dependency. Claims 50-59 have been added. Support for the added claims can be found in the Specification and claims as filed, for example, Claims 1, 6, 21 and 27. Claim 27 was amended to be dependant upon an elected claim. Claims 28-35 and 37-47 have been cancelled. The changes made to the Specification and Claims by the current amendment, including ~~deletions~~ and additions, are shown herein with deletions designated with a strikethrough and additions underlined. No new matter has been added herewith. Upon allowance of the claims, Applicants request rejoinder of Claims 27, 36 and 48 as being dependent upon an allowed claim.

Rejection under 35 U.S.C.§112, second paragraph

The Examiner rejected Claim 23 as indefinite for having insufficient antecedent basis for the recitation "vaccine composition according to claim 20." The claim has been amended to be dependent upon Claim 21, thus rendering the rejection moot.

Rejection under 35 U.S.C.§112, first paragraph – Written Description

Claims 1-4, 6-8, 10-11, 17-20, 22, and 25-26 were rejected under the written description guidelines. More specifically, the Examiner did not believe that the language in Claims 1-4, 6-8, 10-11, and 17-20 reciting: a variant, truncated variant, a peptide comprising an amino acid sequence 70% identical to SEQ ID NO:1, 50% identical to amino acid residues 1-42 of SEQ ID NO:1, and a homologue or derivative, had an adequate description in the Specification. The claims include the following functional language to describe the variants: "wherein said variant mimics or cross-reacts with a B-cell or T-cell epitope of *Lawsonia spp* SodC polypeptide."

The test for sufficiency of support under the written description requirement of 35 U.S.C. §112, first paragraph is whether the disclosure "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." This depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure.

The Examiner states that the specification fails to disclose any substitution, insertion or deletion or change in (i) a polypeptide SEQ ID NO:1 to obtain a variant having 70% or 50%

identify to SEQ ID NO:1 or variants or homologues of SEQ ID NO:1. The Examiner goes on to state that the Specification does not describe any use of such variants as claimed in identifying *L. intracellularis* infection.

However, the Specification provides considerable teaching of various types of variants and methods of producing the variants as claimed. For example, Figure 1 provides an amino acid alignment of various SOD polypeptides known in the art. This alignment clearly shows areas of high conservation and areas of low conservation. The amino acids recognized as critical for the function of SODC are shown with an asterisk (see Brief Description of the Drawings, Figure 1). This, in combination with the explanation of which areas are useful for immune polypeptides (page 17, paragraph 3), that the N-terminus is particularly unique between organisms (page 24, paragraph 3 and 4, substitution variants (page 20 last paragraph through page 21 last complete paragraph), and teachings as to the types of changes that can affect the epitope (page 9, first paragraph and page 13, second paragraph), give the skilled artisan sufficient information about variants that would still "cross react with a B-cell or T-cell epitope of *Lawsonia spp.* SodC Polypeptide." Once produced or identified, the Specification teaches how variants can be tested for cross-reactivity using the methods on page 22, lines 8-20.

Thus, the specification provides specific teaching on the parts of SodC that are most conserved among organisms, the areas that would be most useful for antigenicity, and the areas that are most unique. The specification then provides further information providing the types of mutations or changes that would be useful and/or accepted while still retaining antigenicity. The specification provides methods of testing the variants for cross-reactivity to SodC. Lastly, the specification provides methods of using the polypeptides as vaccines for the treatment and prophylaxis of *L. intracellularis* infection.

Because the field of vaccination and immunization is historically one of the earliest aspects of molecular biology to be formed, it has had a lengthy amount of time to gain a certain sophistication, while fields like immunology have lagged. Thus, the skilled artisan can be considered quite knowledgeable. Although working examples of variants and truncated variants have not been provided in the specification, the amount of guidance which has been provided gives the skilled artisan more than enough support to isolate and identify variants and truncated variants. Thus, Applicants respectfully request withdrawal of the rejection under 35 U.S.C.§112, first paragraph.

Rejection under 35 U.S.C.§112, first paragraph – Enablement

Claims 1-4, 6-8, 10-11, 17-23, 25-26, and 49 were rejected as not being enabled by the specification. The Examiner states that the specification does not provide an enabling disclosure for variants, but does enable an isolated polypeptide or recombinant immunogenic polypeptide comprising the amino acid sequence SEQ ID NO:1 or the amino acid sequence encoded by the SodC encoding nucleotide sequence of PALK14 or an immunogenic composition comprising these. The test for enablement involves determining whether undue experimentation is required to practice the claimed invention.

A variety of guidelines are used to identify whether undue experimentation is required to identify variants, including, the teaching in the specification, the number of known variants, and the knowledge of one of skill in the art. As stated above with respect to the written description rejection, the amount of teaching in the specification is extensive, so, although there are no known variants, one of skill in the art would have sufficient teaching in the Specification to make and identify variants. In addition, the art of vaccination/immunization is one of the most sophisticated in molecular biology and, given the recent advances in the science of molecular biology, the unpredictability of this art has lessened significantly. As a result, the number of experiments necessary to determine a particular result is now low, and these experiments have become routine in the art.

Deposit

Claims 13, 14 and 23 have been rejected because they include a deposit description without a promise for availability. As suggested by the Examiner, a statement by the agent of record stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public will be irrevocably removed upon the granting of a patent is included hereinbelow, thus rendering the rejection moot.

This deposit was made under the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure and the Regulations thereunder (Budapest Treaty). This assures maintenance of a viable culture of the deposit for 30 years from the date of deposit. The deposit will be made available by ATCC under the terms of the Budapest Treaty, which assures that all restrictions imposed by the depositor on

the availability to the public of the deposited material will be irrevocably removed upon the granting of the pertinent U.S. patent, assures permanent and unrestricted availability of the progeny of the culture of the deposit to the public upon issuance of the pertinent U.S. patent or upon laying open to the public of any U.S. or foreign patent application, whichever comes first, and assures availability of the progeny to one determined by the U.S. Commissioner of Patents and Trademarks to be entitled thereto according to 35 USC § 122 and the Commissioner's rules pursuant thereto (including 37 CFR § 1.14 with particular reference to 886 OG 638). The assignee of the present application has agreed that if a culture of the cell line on deposit should die or be lost or destroyed when cultivated under suitable conditions, the materials will be promptly replaced on notification with another of the same.

Rejection under 35 U.S.C. §102(b)

The Examiner rejected Claims 1-4, 6-8, 10-11, 17-20, 21-22, and 25-26 as anticipated by McOrist, et al. Infect. Immun. 1989 March; 57 (3):957-962. The Examiner believed that the 20 kD polypeptide isolated/identified by polyacrylamide gel electrophoresis in McOrist et al. is inherently the same as that claimed in independent claims 1, 6, and 21.

> To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

The presently claimed invention is an isolated or recombinant immunogenic polypeptide, comprising a *Lawsonia* SodC polypeptide, variant or truncated variant which mimics or cross-reacts with a B-cell or T-cell epitope of a *Lawsonia spp.* SodC polypeptide.

McOrist et al. provides a protein profile of Campylobacter species which contains a number of different bands from 9 different preparations of various Campylobacter species. The profiles are dominated by major protein bands of 55 and 70 kD, and, as stated on page 959, column 2: "Minor components were recognized between 20,000 and 43,000 kD..." There is no specific reference to a 20 kD protein and the minor components between 20 and 43 kD did not

appear in all lanes. Further, with reference to the immunoblot using antiserum from rabbits injected with formalin-fixed whole cell antigen, only a 25K and 27K component with some recognition of the 55K and 43K bands in some preparations was identified. No 20 kD band was identified by immunoblot.

The Examiner states that "it is inherent that the 20 kD antigen isolated/identified by polyacrylamide gel electrophoresis procedure is the same as the claimed polypeptide." However, according to the MPEP §2112 IV. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill". The Examiner must provide rationale or evidence tending to show inherency. "The Fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency..."

The Examiner's identification of a possible band on an SDS PAGE gel between 20 and 40 kD which was identified as a minor component in a protein profile does not constitute evidence to show inherency. Due to the inexact nature of SDS PAGE gels, this band could have had a molecular weight varying between 18 and 24kD. Further, the band that the Examiner identifies was not found to be identified by immune serum from an animal, suggesting to the skilled artisan that it was not immunogenic. Thus, even if the band were 20 kD, it was not shown upon further analysis by immunoblot as likely to be immunogenic. The polypeptide recited in the presently pending claims are immunogenic. Thus, whatever the "20 kD antigen" isolated by McOrist is, it is unlikely to represent the polypeptide recited in the presently pending claims.

Thus, Applicants submit that a band between 20 and 40 kD which does not show up on an immunoblot is not inherently the same as an isolated immunogenic SodC polypeptide as claimed herein and Applicants respectfully request withdrawal of the novelty rejection.

Conclusion

Applicants believe that the current amendments place the application in condition for allowance. Should there be any questions which might result in a delay in allowance, the examiner is respectfully requested to contact the undersigned at the telephone number appearing

below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: May 12, 2005

By: Jennifer Haynes

Jennifer A. Haynes, Ph.D.
Registration No. 48,868
Agent of Record
Customer No. 20,995
(415) 954-4114

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